IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

M. MARGARET PATTERSON and
WAYNE PATTERSON,
692 Old Post Road
North Attleboro, MA 02760

PLAINTIFFS,

v.

NOVARTIS PHARMACEUTICALS CORPORATION, AAP PHARMACEUTICALS, INC., BEDFORD LABORATORIES, HOSPIRA, INC., TEVA PARENTERAL MEDICINES, INC., AESGEN, INC., AKORN, INC., CIPLA LTD., and SANDOZ, INC.,

DEFENDANTS.

Case No. _____

JURY DEMANDED

COMPLAINT AND JURY DEMAND

NOW COME plaintiffs M. Margaret Patterson ("Mrs. Patterson") and Wayne Patterson ("Mr. Patterson") (collectively "Plaintiffs"), by and through counsel, and hereby sue the Defendants, Novartis Pharmaceuticals Corporation ("Novartis" or "NPC"), AAP Pharmaceuticals, Inc. ("AAP"), Bedford Laboratories ("Bedford"), Hospira, Inc. ("Hospira"), Teva Parenteral Medicines, Inc. ("Teva"), AESGEN, Inc. ("AESGEN"), Akorn, Inc. ("Akorn"), Cipla, Ltd. ("Cipla"), and Sandoz, Inc. ("Sandoz") (collectively "Defendants"), and for their cause of action state:

I. INTRODUCTION

1. The bisphosphonate drugs Aredia® and Zometa®, each produced and marketed by Novartis and other related Novartis entities, each cause and precipitate osteonecrosis of the jaw, mandible or maxilla bone among patients taking those drugs. Generic Aredia (pamidronate) is produced and marketed by AAP, Bedford, Hospira, Teva, AESGEN, Akorn, Cipla, and Sandoz. Osteonecrosis is bone death of an area of the bone. Osteonecrosis of the jaw is a permanently disfiguring and extremely painful condition, and can result in the complete loss of the patient's jaw bone. Plaintiff Mrs. Patterson in this action was infused with Aredia® and/or generic Aredia (pamidronate) and has suffered osteonecrosis of the jaw bone.

II. PARTIES

A. PLAINTIFFS

2. Plaintiff M. Margaret Patterson is a citizen and resident of the State of Massachusetts, residing in North Attleboro, Massachusetts. She was prescribed, purchased, and was infused with Aredia® and/or generic Aredia (pamidronate) and as a result thereof suffered severe osteonecrosis of the jaw, including pain, infection, and disfigurement. As is the case with all patients suffering from this condition, Mrs. Patterson is at risk for needing invasive procedures or surgeries in the future should her condition require it or should it deteriorate further.

3. Plaintiff, Wayne Patterson, is the husband of Plaintiff M. Margaret Patterson. Mr. Patterson resides with his wife and is a citizen and resident of the State of Massachusetts, residing in North Attleboro, Massachusetts.

B. DEFENDANTS

4. Defendant Novartis is a non-resident corporation with its corporate headquarters located at 1 Health Plaza, East Hanover, New Jersey, 07936-1080.

5. At all times relevant hereto, Novartis was engaged in the business of marketing, distributing, promoting, testing, labeling and selling the drugs Aredia® and Zometa®. Novartis, at present or in the past, markets and distributes Aredia® and Zometa® throughout the world, including all fifty states in the United States, and throughout Massachusetts.

6. Defendant APP is a non-resident corporation with its corporate headquarters located at 1501 East Woodfield Road, Suite 300 East, Schaumburg, Illinois 60173-5837.

7. At all times relevant hereto, APP was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Abraxis at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

8. Defendant Bedford is a non-resident corporation with its corporate headquarters located at 300 Northfield Road, Bedford, Ohio 44146.

9. At all times relevant hereto, Bedford was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Bedford at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world, including all fifty states in the United States, and every county in Massachusetts.

10. Defendant Hospira is a non-resident corporation with its corporate headquarters located at 275 North Field Drive, Lake Forest, Illinois 60045.

11. At all times relevant hereto, Hospira was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Hospira at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

12. Defendant Teva is a non-resident corporation with its corporate headquarters located at 19 Hughes, Irvine, California 92618.

13. At all times relevant hereto, Teva was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Teva at present or in the past, markets and distributes generic

Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

14. Defendant AESGEN is a non-resident corporation with its corporate headquarters located at 2 Research Way, Princeton, New Jersey 08544.

15. At all times relevant hereto, AESGEN was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). AESGEN at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

16. Defendant Akorn is a non-resident corporation with its corporate headquarters located at 1925 West Field Court, Suite 300, Lake Forest, Illinois 60045.

17. At all times relevant hereto, Akorn was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Akorn at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

18. Defendant Cipla is a non-resident corporation with its corporate

headquarters located at Mumbai Central, Mumbai, India 400 008.

19. At all times relevant hereto, Cipla was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Cipla at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

20. Defendant Sandoz is a non-resident corporation with its corporate headquarters located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

21. At all times relevant hereto, Sandoz was engaged in the business of marketing, distributing, promoting, testing, labeling and selling generic Aredia (pamidronate). Sandoz at present or in the past, markets and distributes generic Aredia (pamidronate) throughout the world including all fifty states in the United States, and every county in Massachusetts.

III. JURISDICTION AND VENUE

22. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by individual Plaintiffs who are citizens of a different state from all the Defendants. Venue is proper in this

District pursuant to 28 U.S.C. §§ 1391(a) and 1391(c).

IV. FACTUAL BACKGROUND

23. Aredia®, generic Aredia (pamidronate), and Zometa® are classified as bisphosphonates and are prescribed for the management of metastatic disease to the bone and other bone diseases and conditions. Zometa® is NPC's "successor" drug to Aredia®, as Aredia® was the first generation version of the drug Zometa®. Zometa® is now marketed by NPC for all or almost of the uses for which it previously marketed Aredia®. Aredia®, generic Aredia (pamidronate), and Zometa® have been approved by the United States Food and Drug Administration.

24. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia®); zoledronic acid or zoledronate (Zometa®); ibandronate (Bondronat®); risedronate sodium (Actonel®); and alendronate (Fosamax®). The non-nitrogenous bisphosphonates include the following: etidronate (Didronel®); clodronate (Bonefos® and Loron®); and tiludronate (Skelid®). Aredia®, generic Aredia (pamidronate), and Zometa® contain a nitrogen atom, whereas etidronate, clodronate, and tiludronate do not.

25. Studies and medical practices report the frequent and common

occurrence of osteonecrosis of the jaw in the users of the nitrogenous bisphosphonates, including Aredia®, generic Aredia (pamidronate), and Zometa®.

26. The Defendants knew or should have known of the disease phosphorus necrosis of the jaw or "phossy jaw," which appeared in the 1800s in persons mining white phosphorus and persons working in white phosphorus match factories. Phossy jaw had been nearly eliminated in the last century through industrial hygiene. The operation of the active ingredients in Aredia®, generic Aredia (pamidronate), and Zometa® acts and has the same effect as the phosphorus byproducts that caused "phossy jaw." It was foreseeable that any drug with the characteristics of Aredia®, generic Aredia (pamidronate), and Zometa® would carry the risk of a "phossy jaw"-like reaction.

27. The process by which old bone is taken away and new bone is created is called "remodeling." Aredia®, generic Aredia (pamidronate), and Zometa® were all designed specifically to affect the "remodeling" process. Medical science knew, and therefore the Defendants knew or should have known, that the jaw operates differently from other bones in the body in that it is subject to unique stresses, and accordingly "remodels" at a far, far greater rate than other bones in the body. Medical science knew, and therefore the Defendants knew or should have known, that bisphosphonate drugs have a "site preference" for high remodeling areas, and

therefore would have a heightened effect on bones that remodel at a higher rate. Despite this knowledge not one dentist, maxillofacial surgeon, or other jaw or mouth bone specialist was used or assigned to any clinical trial done by NPC for either Aredia® or Zometa®. This failure constituted a design flaw in every clinical trial and tainted all information provided to the FDA, other regulatory authorities, and peer reviewed journals. Nonetheless, despite any intention of examining the jaw or mouth and without utilization of any oral specialists in the clinical trials, NPC's data captured at least six persons who self-reported ONJ-like symptoms in the Zometa® clinical trials. NPC failed properly to report this to the FDA as part of Novartis's application for approval to market the drug, and further failed to report other adverse event reports to the FDA in a timely manner.

28. The Defendants knew and or should have known that bisphosphonates, including Aredia®, generic Aredia (pamidronate), and Zometa®, inhibit the activity of osteoclasts in the bone. Similarly, the Defendants knew or should have known that bisphosphonates cause changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these changes appear to be cumulative in nature.

29. The Defendants also knew or should have known that these factors

can progress to jaw necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

30. On information and belief, in the year 2002 or before, NPC was notified by one physician that he had dozens of cases in which patients taking Aredia® had experienced problems so severe that they had lost portions of their jaws. Other oral surgeons during that time frame and before had been reporting such problems to NPC. On information and belief, NPC had similar information as to adverse effects caused by its drug Zometa®, which has similar properties and effects as Aredia® and is marketed by NPC as a more effective replacement for Aredia®. Nevertheless, NPC did not undertake to advise physicians, notify the consuming public or place information about the possibility of suffering osteonecrosis of the jaw on their products until September of 2004. NPC did not undertake to notify dental professionals until May of 2005. These efforts to date by NPC to provide notice are not adequate to provide the public and health care professionals with the information needed to understand the risks inherent in the use of Aredia® and Zometa®, and indeed are themselves false and misleading.

31. Shortly after NPC began selling Zometa®, reports of osteonecrosis of the jaw and other dental complications among users further exploded, indicating that Zometa® shared the class effects of the other nitrogenous bisphosphonates

including Aredia® and generic Aredia (pamidronate). Despite this knowledge, NPC failed to implement further study of the risk of osteonecrosis of the jaw relative to Zometa® and Aredia®. Rather than evaluating and verifying the safety of Zometa® with respect to osteonecrosis of the jaw, NPC proposed further uses of Zometa®, notably for osteoporosis under the names Reclast® or Aclasta® or other names, and upon information and belief, urged off-label uses on medical practitioners. Indeed, hundreds of articles have been written by qualified medical professionals and institutions and published in the top medical journals in the world demonstrating that Aredia® and generic Aredia (pamidronate) causes osteonecrosis of the jaw at a significant rate, and that Zometa® causes osteonecrosis of the jaw at an even higher rate.

32. Rather than warn patients and the medical community, and despite knowledge by NPC of increased risk of osteonecrosis of the jaw in patients using Zometa®, NPC continued and continues to defend and aggressively market Zometa®, while downplaying any unfavorable findings and overstating its benefits. This includes attempting to have it approved for use in the treatment of osteoporosis, and in seeking approval to market the drug for osteoporosis changing the name of the drug to "Reclast®" or "Aclasta®" or other names in order to conceal

the link between the drug and osteonecrosis of the jaw.

33. Because of the long "half-life" of the drugs Aredia® , generic Aredia (pamidronate), and Zometa® in the body, the drug remains in the bones of persons who have been infused with it for at least many, many years or even permanently. For this reason, onset of osteonecrosis of the jaw or worsening of a patient's condition can occur years after infusions of the drug have been discontinued. For this reason, the label indications that call for an infusion of the drug every three-four weeks in perpetuity constitute an overdose.

34. Despite knowledge of the specific risk, the Defendants have failed timely to initiate studies to further investigate risks associated with the use of Aredia®, and/or generic Aredia (pamidronate), and Zometa®.

35. Further, NPC had a duty fully to test and evaluate Aredia® and Zometa® prior to their introduction to the market, to ensure that the drugs were safe to use for their intended purpose. NPC failed to satisfy this duty.

36. Upon information and belief NPC's Safety Reporting System (also known as "STL") generated errors and affected the reporting of safety data to the FDA and negatively impacted clinical trials. To date the system is obsolete and still generating inaccurate safety data that is being submitted to the FDA.

37. NPC failed properly to conduct "dosing studies" to ascertain the

minimum effective quantities of the drugs Aredia® and Zometa®, and thereby to establish the proper quantities of the drugs to be administered to patients and the proper number of infusions which patients should receive. Identifying the minimum effective dosage and setting the dosage instructions accordingly are critical to avoiding the occurrence of side effects. NPC, to maximize profit, for most or all label indications specified a dosage and dosing schedule of Zometa® far above any indicated for palliative effect. This dosing schedule, for most indications, calls for an infusion of the drug every three to four weeks ***forever***, without any end point or time at which the use of the drug should be discontinued. As a result of NPC's failure to instruct as to the proper dosage, upon information and belief the amount of the drug actually administered to Mrs. Patterson constituted an overdose, and contributed to the side effects and harm she suffered.

COUNT I
STRICT LIABILITY

38. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

39. The Defendants were engaged in the business of manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising and otherwise distributing Aredia® and/or generic Aredia (pamidronate) in interstate commerce, which they sold and distributed throughout

the world, including the State of Massachusetts.

40. Mrs. Patterson was using Aredia® and/or generic Aredia (pamidronate) in the manner for which they were intended, or in a reasonably foreseeable manner.

41. Aredia® and/or generic Aredia (pamidronate) were expected to and did reach Mrs. Patterson without substantial change in their condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised and otherwise distributed.

42. Mrs. Patterson was not aware of, and reasonably could not have discovered, the actual dangerous nature of Aredia® and/or generic Aredia (pamidronate).

43. Aredia® and/or generic Aredia (pamidronate) cause increased risks of osteonecrosis of the jaw upon consumption, and therefore constitute products unreasonably dangerous for normal use due to their defective design, defective manufacture, and the Defendants' misrepresentations and inadequate facts disclosed to Mrs. Patterson and her health care providers including, *inter alia*, the actual risk of developing osteonecrosis of the jaw and the permanent, irreversible harm associated with this disease.

44. As a direct and proximate result of the Defendants' manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing,

selling, advertising, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) in interstate commerce, Mrs. Patterson has suffered osteonecrosis of the jaw, and is at an increased risk of developing other diseases and conditions.

45. The Defendants, therefore, are strictly liable to Mrs. Patterson and Mrs. Patterson is entitled to compensatory damages. Additionally, the Defendants' conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. Mrs. Patterson therefore is entitled to punitive damages in an amount to be proven at trial.

COUNT II
NEGLIGENCE - NEGLIGENT MANUFACTURE

46. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

47. It was the duty of the Defendants to use reasonable care in the manufacturing, creating, designing, testing, sterilizing, packaging, supplying, and otherwise distributing Aredia® and/or generic Aredia (pamidronate).

48. Contrary to their duty, the Defendants failed: adequately and properly to test and inspect Aredia® and/or generic Aredia (pamidronate) so as to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured and sold; adequately and properly to conduct a dosing study or otherwise to test Aredia® and/or generic Aredia (pamidronate) to ascertain

the minimum effective dosage and to use this information to instruct users of the drugs and/or their health care providers of the proper dosage so as to minimize the risk of development of osteonecrosis of jaw or other side effects; to utilize and/or implement a reasonably safe design in the manufacture of Aredia® and/or generic Aredia (pamidronate); to manufacture Aredia® and/or generic Aredia (pamidronate) in a reasonably safe condition appropriate for the use for which they were intended.

49. The Defendants manufactured and sold Aredia® and/or generic Aredia (pamidronate), which as constituted are and were a hazard to Plaintiff's health. The Defendants' manufacture and sale of Aredia® and/or generic Aredia (pamidronate) as constituted caused Mrs. Patterson to suffer adverse side effects and disease.

50. The Defendants were otherwise careless and negligent.

51. As a direct and proximate result of the Defendants' negligent, reckless, and careless manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, and otherwise distributing Aredia® and/or generic Aredia (pamidronate) in interstate commerce, Mrs. Patterson has suffered osteonecrosis of the jaw, is at an increased risk of developing other diseases and conditions, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT III
NEGLIENCE – FAILURE TO WARN

52. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

53. It was the duty of the Defendants to use reasonable care in the labeling, marketing, selling, advertising, and promoting of Aredia® and/or generic Aredia (pamidronate), and to warn Mrs. Patterson and her medical providers of the true risk of osteonecrosis of the jaw and other side effects when using the Defendants' drug.

54. Contrary to its duty, the Defendants failed: adequately and properly to warn Mrs. Patterson of the risks of serious complications and bodily harm when Aredia® and/or generic Aredia (pamidronate) are used in the manner for which they were intended; adequately and properly to warn Mrs. Patterson of the risks of diseases when Aredia® and/or generic Aredia (pamidronate) are used in a manner for which they were intended; adequately and properly to label Aredia® and/or generic Aredia (pamidronate) so as to warn Mrs. Patterson of the risks of complications and disease; and adequately and properly to label Aredia® and/or generic Aredia (pamidronate) so as to warn Mrs. Patterson of the risks of osteonecrosis of the jaw.

55. Further, the Defendants failed to meet the standard of care set by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq., related

amendments and codes and federal regulations provided thereunder, the Sherman Food, Drug and Cosmetic Law, and other applicable laws, statutes and regulations. The Defendants further failed in the following respects:

a. The labeling lacked adequate information on the use of the drugs Aredia® and/or generic Aredia (pamidronate) (21 C.F.R. Section 201.56(a) and (d));

b. The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitation, osteonecrosis of the jaw, and other adverse medical conditions as soon as there was reasonable evidence of their association with the drugs (21 C.F.R. 201.57(e));

c. There was inadequate information for patients for the safe and effective use of the Defendants' drugs (21 C.F.R 201.57(f)(2));

d. There was inadequate information regarding special care to be exercised by Mrs. Patterson's doctors for safe and effective use of the Defendants' drugs (21 C.F.R. 201.57(f)(1));

e. The labeling was misleading and promotional (21 C.F.R. 201.56(b)); and

f. The Defendants' acts constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331.

56. The Defendants' products Aredia® and/or generic Aredia (pamidronate) were unaccompanied by proper and adequate warnings regarding the risk of osteonecrosis of the jaw associated with the use of the Defendants' products and the scope, severity and duration of such injuries.

57. Despite the Defendants' failure to provide adequate warnings to protect users or consumers of Aredia® and/or generic Aredia (pamidronate), the

Defendants nevertheless continued aggressively to market, promote, distribute, and sell the dangerously defective products.

58. As a result of the Defendants' negligence and the violations of the statutes and regulations listed above, Mrs. Patterson suffered injuries and damages as alleged herein.

59. As a direct and proximate result of the Defendants' failure to warn, Mrs. Patterson has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT IV
BREACH OF EXPRESS WARRANTY

60. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

61. The Defendants expressly warranted to Mrs. Patterson, by and through statements made by the Defendants or their authorized agents or sales representative, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Aredia® and/or generic Aredia (pamidronate) were safe, effective, fit and proper for their intended use.

62. In using Aredia® and/or generic Aredia (pamidronate), Mrs. Patterson

and her health care providers relied on the skill, judgment, representations and foregoing express warranties of the Defendants. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

63. As a direct and proximate result of the Defendants' breaches of warranties, Mrs. Patterson has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT V
BREACH OF IMPLIED WARRANTY

64. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

65. Prior to the time that Aredia® and/or generic Aredia (pamidronate) were used by Mrs. Patterson, the Defendants impliedly warranted to Mrs. Patterson that Aredia® and/or generic Aredia (pamidronate) were of merchantable quality and safe and fit for the use for which they were intended. Mrs. Patterson is unskilled in the research, design and manufacture of Aredia® and/or generic Aredia (pamidronate), and reasonably relied on the skill, judgment and implied warranty of the Defendants in using Aredia® and/or generic Aredia (pamidronate).

66. Aredia® and/or generic Aredia (pamidronate) were neither safe for

their intended use nor of merchantable quality, as warranted by the Defendants, in that they had dangerous propensities when put to their intended use and would cause severe injuries to the user.

67. As a direct and proximate result of the Defendants' breaches of warranties, Mrs. Patterson has developed osteonecrosis of the jaw, is at risk of developing other diseases, and has suffered compensatory damages and is entitled to punitive damages in amounts to be proven at trial.

COUNT VI
LOSS OF CONSORTIUM

68. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:

69. As a proximate cause of the Defendants' wrongful conduct resulting in the injuries Plaintiffs have suffered as described herein, Mr. Patterson has lost the spousal consortium of Mrs. Patterson. He will likely continue to lose his spouse's consortium in the future due to the Defendants' wrongful conduct.

70. Accordingly, Mr. Patterson has suffered compensatory damages in an amount to be proven at trial. Mr. Patterson hereby avers that the acts committed by Defendants, and their willful and wanton acts and legal malice constitute aggravating factors which support an award of punitive damages.

WHEREFORE, Plaintiffs pray that this honorable Court enter judgment against Novartis, and in favor of the Plaintiffs, and to award the following relief:

a. Award Mrs. Patterson all damages allowed by law to compensate her for the physical injury, pain, suffering, emotional distress, mental anguish, physical disability and physical disfigurement and other losses which she has endured;

b. Award Mrs. Patterson damages equal to the amount of her medical and health care costs and expenses incurred to present and in the future;

c. Award Mrs. Patterson damages in an amount sufficient to compensate her for the likely future deterioration of her medical condition as a result of the harm she has suffered from use of the Defendants' products;

d. Award Mr. Patterson damages for loss of companionship and consortium with his spouse;

e. Award Plaintiffs damages equal to any amount of lost wages and earnings;

f. Award Plaintiffs punitive/exemplary damages to the extent necessary and appropriate to punish and deter the conduct complained of herein;

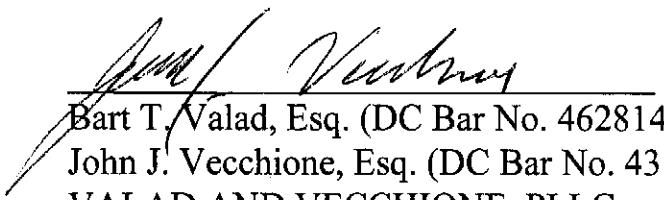
g. Award Plaintiffs attorneys' fees and costs, plus interest, as allowed by law; and

h. Award Plaintiffs such other and further legal and equitable relief as this honorable Court deems just and proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury of this action.

VALAD & VECCHIONE, PLLC



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